Exhibit D

EXPERT REPORT OF KEVIN G. McANANEY

May 3, 2021

Filed on behalf of Defendant Gilead Sciences, Inc. in
United States ex rel. Chris Purcell and Kimberly Groome v. Gilead Sciences, Inc.
Case No. 17-cv-3523 (MAK)

Contents

I. SUMMARY OF FINDINGS

This report analyzes the application of relevant government and industry compliance guidance applicable to the pharmaceutical industry to the compliance program and practices of Gilead Sciences, Inc. ("Gilead") during the time period of 2013 – 2019 (the relevant time period of this litigation; hereinafter "Relevant Period"). This analysis demonstrates that Gilead had an effective compliance program that was consistent with—and often exceeded—government and industry guidance and standards. Gilead had an appropriately sized and well-resourced compliance department. Its compliance controls for speaker programs and advisory board programs met or exceeded applicable standards. The controls were effectively implemented in practice. Moreover, occasional deficiencies in complying with controls are inevitable and do not render an entire compliance program ineffective.

II. BACKGROUND

I am an attorney specializing in federal health care fraud and abuse policy and regulation. I have over 25 years of experience in health care regulation, including substantial experience working within the federal government. During my time working in the federal government, I assisted in the implementation and enforcement of the federal anti-kickback statute ("AKS" —42 U.S.C. § 1320a-7b(b)—and on legal and regulatory guidance applying the AKS to various health care industry sectors.

I served as the Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of the United States Department of Health and Human Services ("HHS") from 1997 until 2003. In that position, I was responsible for drafting and issuing formal guidance to the regulated community through advisory opinions, fraud alerts, special bulletins, compliance program guidance documents, and regulations related to the fraud and abuse statutes and regulations enforced by the HHS Office of Inspector General ("OIG"), including the AKS and the physician self-referral law, 42 U.S.C. § 1395nn (commonly known as the "Stark Law").

I am thoroughly familiar with the substance and development of both the PhRMA Code on Interactions with Health Care Professionals and HHS OIG's Compliance Program Guidance ("CPG") for Pharmaceutical Manufacturers. As Chief of the Industry Guidance Branch, I was responsible for drafting sections of the CPG related to AKS risk for pharmaceutical companies, including consulting and advisory arrangements with health care professionals ("HCPs").

I have been qualified and served as a compliance expert for the OIG's corporate integrity agreement ("CIA") with Amerigroup as required by Amerigroup's settlement of litigation under the civil False Claims Act. My duties included advising the Compliance Committee of the Amerigroup Board of Directors regarding the effectiveness of the company's compliance program.

Since 2003 I have been in private practice, specializing in the Stark Law and AKS. In that capacity, I have had extensive experience counseling health care entities—including pharmaceutical manufacturers, health systems, and academic medical centers—on their arrangements with physicians, reviewing their compliance policies regarding such arrangements, and structuring such arrangements to comply with the Stark Law and AKS. I was an adjunct professor of law at the University of Maryland Law School from 2002 until 2015, where I taught a course in health care fraud and abuse regulation. I am also a former member of the Board of Directors of the American Health Lawyers Association and a frequent speaker on health care fraud issues.

My curriculum vitae is attached as Appendix A. The matters in which I have given deposition or trial testimony as an expert witness in the last four years are set forth in Appendix B. I have authored one publication within the last 10 years.[1]

I have been engaged by Orrick, Herrington & Sutcliffe LLP on behalf of Gilead to serve as an expert in *United States ex rel. Chris Purcell and Kimberly Groome v. Gilead Sciences, Inc.*, Case No. 17-cv-3523 (MAK). I am being compensated at $600 per hour for my time. My compensation is not contingent in any way on the outcome of this litigation. I have reviewed certain documents that counsel for Gilead has provided me, as specifically set forth in Appendix C to this report. I have not undertaken any independent investigation. I have also reviewed the relevant statutes, regulations, preambles, and government guidance related to the AKS.

The scope of my engagement was to review the relevant compliance guidance applicable to the pharmaceutical industry during the Relevant Period and to apply that guidance in assessing Gilead's compliance program and practices during the same time period. In particular, I have applied relevant guidance to Gilead's speaker programs and advisory board programs, which I understand to be the primary focus of Relators' allegations in this case. I reserve the right to modify or amend this report based on further discovery in the litigation.

III. GOVERNMENT AND INDUSTRY GUIDANCE ON PHARMACEUTICAL COMPANY COMPLIANCE PROGRAMS

The False Claims Act (also known as the "Lincoln Law") has prohibited the submission of false monetary claims to the United States government since 1863. The advent of the corporate compliance program, however, has been much more recent. In the United States, compliance programs originated in the 1980s in the defense industry in response to highly publicized reports of inflated charges to the government for mundane parts (such as toilet seats). In the mid-1990s, the HHS OIG began promoting voluntary compliance programs to the health care industry. Since then, the federal government has increasingly expected companies that receive substantial revenue from government sources to take appropriate steps to prevent their employees from violating federal law. Thus, company-wide programs to prevent and identify potential violations of federal laws have become commonplace across industries, including for pharmaceutical companies.

Pharmaceutical compliance programs are generally intended to promote compliance and prevent violations of laws and regulations. Various industry groups and government entities have promulgated compliance program guidance for pharmaceutical companies. An occasional failure of an individual employee to strictly follow compliance policies does not mean that the company's compliance program is ineffective or that the failure necessarily violates the law. Even the best compliance programs cannot eliminate all policy violations.

a. *2002 PhRMA Code*

In March 2002, the Pharmaceutical Research and Manufacturers Association ("PhRMA")—an industry trade group—issued its Code on Interactions with Health Care Professionals (the "PhRMA Code"). The PhRMA Code is intended to ensure that relationships between PhRMA-member pharmaceutical companies and HCPs follow the highest ethical standards and comply

[1] Kevin G. McAnaney, "Permissibility of Pharmaceutical Copayment Coupon Programs Under ACA," BNA's Health Care Fraud Report, August 21, 2013.

with relevant legal requirements.[2] The PhRMA Code established guidance on various common arrangements between pharmaceutical companies and HCPs to whom they market products, including research, speaker bureaus, advisory roles, and business courtesies (such as complimentary meals, entertainment, and gifts). The PhRMA code is voluntary. It focused on *policy guidance* that member companies could implement to meet the ethical expectations of the group.

The PhRMA Code recognizes and provides for HCP participation in company-sponsored speaker programs to educate and inform other HCPs about the benefits, risks, and appropriate uses of company medicines.[3] The 2002 PhRMA Code provided the following specific to company-sponsored speaker programs:

- Informational presentations were recognized as legitimate and valuable services to the pharmaceutical industry;
- Such meetings could include a modest meal in a venue conducive to discussion;
- Attendees should not include spouses of the HCPs;
- Speakers should have a written contract setting out the services they are expected to render and the compensation they would receive for those services, including compensation for any necessary speaker training;
- Companies should have policies to:
    - determine the legitimate need for the services prior to entering into any arrangement;
    - establish the qualifications necessary for speakers to meet that need and company personnel able to ascertain those qualifications;
    - limit such arrangements to the number of speakers reasonably necessary to achieve the purpose;
    - utilize the contracted-for speakers' services.

b. *OIG Guidance*

The HHS OIG issued its first CPG in 1997 for the clinical laboratory industry, which was then the subject of several major False Claims Act cases arising out of allegations of false billing. Between 1997 and 2003, the OIG issued 11 CPG documents for specific health care industry segments, including hospitals, billing companies, clinical laboratories, and physician practices.

In 2003, the OIG issued its CPG for Pharmaceutical Manufacturers, the purpose of which was to "encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements."[4] The OIG's guidance expanded beyond the policy expectations of the PhRMA Code to address broader elements of a compliance program in practice. The OIG wrote: "this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to

[2] PhRMA Code on Interactions with Health Care Professionals at 1 (April 19, 2002) (hereinafter the "2002 PhRMA Code").
[3] *Id.* at 9.
[4] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

applicable rules and program requirements." The CPG goes on to note that the guidance is not "viewed as mandatory" but is designed to address functions that "have been widely recognized as fundamental to an effective compliance program."[5] The CPG sets out seven elements fundamental to effective compliance programs:[6]

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

The CPG provided the following specific guidance on consulting arrangements with HCPs:

> "Pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer. In general, fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a passive capacity is suspect.
>
> Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or ''shadowing'' services.
>
> …
>
> At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) the arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment. In addition, to further reduce their risk, manufacturers should structure services arrangements to comply with a safe harbor whenever possible."[7]

The OIG noted that compliance with the PhRMA Code would significantly reduce a manufacturer's risk that speaker arrangements would violate the AKS:

> "[T]hese arrangements [with physicians] potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company. While the determination of whether a particular arrangement violates the anti-

[5] *Id.*
[6] *Id.*
[7] *Id.* at 23,738.

> kickback statute depends on the specific facts and circumstances, compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk."[8]

During the Relevant Period, the applicable safe harbor for consulting arrangements was the personal services arrangement safe harbor[9] ("Safe Harbor"). During the Relevant Period, the Safe Harbor protected arrangements that met the following conditions:

- The agreement is set out in writing and signed by the parties;
- The agreement specifies all of the services to be provided for the term of the agreement;
- If the services are provided on a periodic, sporadic, or part-time basis, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- The term of the agreement is for not less than one year;
- The aggregate compensation paid to the agent over the term of the agreement is:
  - set in advance;
  - consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any federal health care referrals or business otherwise generated between the parties;
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Effective January 19, 2021, the Safe Harbor was modified to eliminate the requirement that contracts for part time arrangements had to specify the exact schedule for when the services would be provided.[10] The new regulation also eliminates the requirement that the total aggregate compensation be specified in the contract and simply requires that methodology for determining the compensation be specified in the contract.

Finally, "[t]he OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as well as federal health care program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior."[11]

---

[8] *Id.* The OIG also stated that compliance with the PhRMA Code would "demonstrate a good faith effort to comply with the applicable federal health care program requirements." *Id.* at 23737.
[9] 42 C.F.R § 1001.952(d).
[10] Medicare and State Health Care Programs: Fraud and Abuse: Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684-77,895 (Dec. 2, 2020) (to be codified at 42 C.F.R. pts. 1001 & 1003).
[11] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23,732.

c. *2009 Revised PhRMA Code*

Effective January 1, 2009, PhRMA revised and updated its PhRMA Code.[12] The revised code tightened the policies in the 2002 PhRMA Code by:

- Clarifying that resorts were not an appropriate venue for speaker trainings or advisory boards;
- Recommending that companies establish:
  - caps on the aggregate annual payments to speakers;
  - a minimum number of programs to be completed by speakers;
- Training speakers on FDA requirements; and
- Requiring speakers to disclose any conflict of interest.

d. *Corporate Integrity Agreements*

While the OIG has not updated its CPG for pharmaceutical manufacturers since 2003, the OIG has required some companies—including pharmaceutical companies—that settle civil False Claims Act litigation involving allegations of improper incentives to HCPs to enter into Corporate Integrity Agreements. These CIAs are a condition for the companies to remain participants in federal health care programs. CIAs have stringent policy and compliance program requirements to ensure that the companies do not repeat violations of law.

Several of the CIAs entered into by pharmaceutical companies since 2003 require the companies to implement very specific measures with respect to consulting and other arrangements with HCPs. While implementation of such measures is required only of the settling company, companies in similar businesses often voluntarily adopt similar measures in whole or in part.

One of the first CIAs to address pharmaceutical speaker programs involved Allergan in 2010. Allergan had settled a False Claims Act case alleging off-label marketing to physicians. As part of its CIA, the OIG required that Allergan establish policies and procedures with respect to various consulting arrangements with HCPs (such as speakers) to "ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events."[13]

In or around 2013, the OIG modified its CIA provisions with respect to pharmaceutical company speaker programs. The OIG included in its CIAs with pharmaceutical companies' provisions requiring settling companies to establish the following compliance program elements[14]:

- processes to require all speakers to complete training and enter into written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers;

[12] PhRMA Code on Interactions with Health Care Professionals at 2-3 (July 2008) (hereinafter the "2009 PhRMA Code"). The revised PhRMA Code was released in July 2008, to become effective January 1, 2009.
[13] Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc. at 13.
[14] *See generally* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.

- a centralized electronic system through which all speaker programs are administered to establish controls regarding eligibility and qualifications of speakers and venues for the programs and to require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis;
- a comprehensive list of speaker program attendees through the centralized system;
- tracking and reviewing the aggregate amount paid to each speaker in connection with speaker programs;
- evaluations by sales personnel regarding whether a speaker program complied with company requirements, and, in the event of non-compliance, requiring the identification of the policy violation and ensuring appropriate follow-up activity to address the violation;
- a speaker monitoring program under which company compliance personnel who are independent from the functional area being monitored shall attend a representative number of speaker programs and conduct live audits of such programs.

e. *DOJ Guidance*

In 2017, the United States Department of Justice's ("DOJ") Criminal Division published guidance on the evaluation of corporate compliance programs. The DOJ guidance is focused on the compliance program's operation more than on specific policies. Specifically, the guidance focuses on three "fundamental questions" a prosecutor should ask[15]:

- Is the corporation's compliance program well designed?
- Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
- Does the corporation's compliance program work in practice?

DOJ also encourages prosecutors to evaluate the company's risk assessment, risk management processes, and risk-tailored resource allocation.[16] DOJ's guidance also discusses policies and procedures, training and communications, confidential reporting mechanisms, investigative processes, management of third-party relationships, M&A, tone at the top, incentives, disciplinary measures, periodic testing and review, and root cause analyses.[17]

Finally, DOJ also notes that "the existence of misconduct does not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense."[18] Indeed, "[t]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees."[19]

---

[15] Justice Manual § 9-28.800.

[16] U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs ("DOJ Evaluation of Corp. Compliance Programs") (updated June 2020) at 3.

[17] *See generally id.*

[18] DOJ Evaluation of Corp. Compliance Programs at 14.

[19] Justice Manual § 9-28.800. This is in accord with the United States Sentencing Commission's recognition that an effective compliance program can result in reduced penalties in appropriate cases. *See generally* U.S. Sent'g Guidelines Manual ch. 8 (U.S. Sent'g Comm'n 2018). Such compliance and ethics programs should be "reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct." *Id.* § 8B2.1(a).

IV. GILEAD'S COMPLIANCE PROGRAM

At all times during the Relevant Period, Gilead maintained an effective compliance program that was consistent with, conformed to, and often exceeded the standards of government and industry guidance. Gilead operates in a complex and highly regulated business environment covering all aspects of its operations, including manufacturing, drug approval, labeling, pricing, and marketing. Its compliance program must and does address these various compliance risks.

Gilead's compliance program satisfies the seven elements of an effective compliance program as identified by the OIG: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication; (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected offenses and undertaking corrective action.[20]

a. *Written Policies and Procedures*

Gilead has implemented, disseminated, and enforced written policies and procedures addressing the importance of ethical conduct for all employees, ensuring that employees understand their obligation to act in a compliant manner and to report unethical or unlawful conduct by other Gilead employees. Gilead's commitment to compliance is set forth in its Code of Ethics. Other written policies include Gilead's Anti-Bribery and Anti-Corruption Policy and the Business Conduct Manual ("BCM"), among others. Gilead's compliance policies educate its employees about federal and state anti-kickback and false claims laws.[21]

The BCM sets forth specific policies and controls for Gilead's United States operations and addresses evolving risk areas – including related to the FDA, pricing, fraud and abuse, various federal and state reporting requirements, consultant arrangements, and privacy regulations. Gilead's Business Conduct unit disseminates hard copies of the BCM to employees annually, and the BCM is available to all employees at all times via Gilead's internal website and through a mobile phone application available to all field employees.[22] The BCM contains a blanket provision specifically forbidding all personnel from providing HCPs with "anything of value—including but not limited to consulting fees, compensation, grants, or gifts—to induce a healthcare professional….to purchase, prescribe, use or recommend a Gilead product, or to influence formulary status (or to reward any such prior action)."[23] Furthermore, the BCM is not a static document. Gilead's corporate deposition designee (Associate General Counsel for the Liver Disease Business Unit (including HBV)) testified that Gilead reviews regulatory and legal developments to assess whether its policies should be revised or updated, and revises and updates its policies accordingly.[24] Policy changes (as well as general compliance guidance) are discussed at annual sales meetings and new guidance may also be distributed to the affected staff in a field

[20] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23,731.
[21] *See generally* 2013 Business Conduct Manual (Gilead_Purcell_00000001-162).
[22] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 23:19-24:8; Tana Sarntinoranont Deposition Transcript at 82:17-83: 3; David Johnson Deposition Transcript at 71:9-25.
[23] 2013 Business Conduct Manual at 2 (Gilead_Purcell_00000010).
[24] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 145:18-146:11. Gilead issued a revised BCM for each year during the Relevant Period. Where policies remained consistent from the 2013 through 2019 BCMs, this report cites to the 2013 BCM. Where policies change during the Relevant Period, this report cites to each relevant version of the BCM and highlights the specific changes between annual versions of the BCM.

memorandum.[25] Gilead's Business Conduct unit disseminates information about new compliance developments as appropriate between formal trainings.[26]

The Hepatitis B sales force received yearly goals and objectives, which reiterated employees' duties to comply with Gilead's compliance policies. Under their annual goals and objectives, Therapeutic Specialists ("TSs") were expected to achieve compliance with Gilead's speaker program policies.[27] Gilead's Sales Incentive Compensation plan also allowed the company to deny compensation incentives to Sales employees found to have violated Gilead's compliance policies.[28] When Gilead found that a TS in the Hepatitis B franchise failed to properly report all reportable HCPs who attended her speaker programs and failed to ensure the accuracy and completeness of program sign-in sheets, Gilead issued a written warning letter and deemed the TS ineligible for any Incentive Compensation Plan contest for 90 days and ineligible for the company's annual "President's Club" sales reward for the relevant year.[29]

b. *Compliance Program Resources*

Gilead has a dedicated business unit for compliance, which it incorporates into all phases of speaker programs and advisory boards – including planning, speaker and advisor selection, speaker training, monitoring, auditing, and enforcement. Gilead's compliance function is led by a Chief Compliance Officer who reports to the Gilead's Board of Directors and the General Counsel. The compliance function's Business Conduct team is comprised of specialized and experienced health care fraud lawyers who interact with Gilead's business units and educate and monitor compliance within Gilead's business operations. The Business Conduct team also includes non-lawyer compliance professionals who support the Business Conduct attorneys with training, monitoring, auditing, and other ad hoc legal and compliance support.[30] Certain Business Conduct lawyers were assigned to specific business units, including Hepatitis B.[31]

Gilead management appropriately understands and exercises its responsibility to oversee the company's compliance efforts. The Board's Audit Committee has responsibility for regulatory compliance.[32] It discharges that responsibility by receiving regular reports from the head of Internal Audit. In addition, the Nominating and Corporate Governance Committee ("NCGC") oversees healthcare compliance. The NCGC receives quarterly reports from the Chief Compliance Officer in addition to holding quarterly executive sessions. The Company's Senior Risk Committee met at least quarterly during the Relevant Period and received regular reports on healthcare compliance. The membership of the Senior Risk Committee included senior company

[25] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 24:20-25:10; Graham Warden Deposition Transcript at 317:3-14.
[26] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 22:12-23:12; David Johnson Deposition Transcript at 69:3-22.
[27] *See, e.g.*, Gilead_Purcell_00252399 (2016 Therapeutic Specialist Goals and Objectives). Gilead's sales representatives use the title Therapeutic Specialist or "TS."
[28] *See, e.g.*, REL_000449-461 at REL_000451 (2015 Sales Incentive Compensation Plan General Terms and Conditions) ("In the event that Gilead determines that an employee's conduct violated the policies set forth in the [Business Conduct] Manual, Gilead reserves the right, in its sole discretion, to deny a Plan Participant Incentive Compensation or a bonus based upon that violative conduct.").
[29] Gilead_Purcell_00028916.
[30] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 11:15-24.
[31] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 11:15-24.
[32] Gilead Sciences, Inc., Audit Committee Charter (Nov. 4, 2020), http://investors.gilead.com/static-files/6e4e7027-94d2-4b72-8b7a-3524008a8431.

executives such as the Chief Executive Officer, Chief Commercial Officer, Chief Financial Officer, General Counsel, Chief Operating Officer, and others. Finally, the North American Commercial organization operated a senior-level compliance committee with cross-functional membership that met quarterly to inform senior leaders of compliance developments and make relevant decisions.

c. *Training and Education*

Gilead's compliance program has a robust educational component that educates and trains employees on its Code of Ethics and ethical and compliance policies. New hires starting with the HBV sales force received Business Conduct training during new hire onboarding, including training on the AKS and False Claims Act.[33] Field sales employees then receive annual Business Conduct training online (though an e-learning platform) and in-person at National Sales Meetings and Mid-Year Sales Meetings each year.[34] Annual training also included education on the AKS, the False Claims Act, real-life fraud risks identified at Gilead and/or its peer firms, and speaker programs.[35] Where applicable, employee education included knowledge tests to ensure the material is understood and internalized.[36] Training is targeted to the risk areas most relevant to employees and is appropriately tailored across functions. Employees may also receive ad hoc Business Conduct training in response to evolving or newly identified risks and relevant policy revisions.[37]

Timely completion of the annual, online compliance training is included in Gilead's sales representatives' annual performance goals and objectives.[38] Gilead also incorporates informal training opportunities into regular business activities, including through informal coaching, feedback during field rides, and more.[39]

d. *Communication and Culture*

Gilead has created a culture of compliance where its employees can freely share, point out issues, and ask questions about compliance.[40] Gilead has established effective means of communication between and among the compliance function, management, and Gilead employees. There are strong lines of communication between the compliance function and the Sales unit.

[33] *See, e.g.*, Gilead_Purcell_00132422 ("Business Conduct Considerations for HBV" new hire Business Conduct training); Gilead_Purcell_00336849 ("Legal Issues in Pharmaceutical Marketing and Sales" new hire Business Conduct training); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 91:12-92:8 (describing new hire compliance training, including home study materials and live training).
[34] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 82:25-83:16 (describing Hepatitis B compliance training); 85:2-18 (describing Business Conduct training given annually from the main stage at the National Sales Meeting).
[35] Gilead_Purcell_00216626 (2015 National Sales meeting Hepatitis B Business Conduct training, including training related to speaker program compliance); Gilead_Purcell_00276515 (2015 Mid-Year Meeting Hepatitis B Business Conduct training, including discussion of AKS and recent government enforcement); David Johnson Deposition Transcript at 69:23-70:18.
[36] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 90:17-91:9; *e.g.*, Gilead_Purcell_00281544.
[37] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 22:25-23:12 (describing the process to provide ad hoc business conduct training in light of policy revisions).
[38] REL_000389.
[39] Jay Cummings Deposition Transcript at 24:18-25:15; 47:1-7.
[40] David Johnson Deposition Transcript at 240:5-22; Marc Aquino Deposition Transcript at 229:1-25.

Business Conduct representatives regularly interact with business units both proactively and in response to inquiries.[41]

Gilead exhibits a strong tone from the top, with senior commercial employees communicating with employees to reinforce the importance of compliance. For example, the Senior Vice President for Gilead's North American Commercial Organization communicated key compliance requirements with respect to speaker programs to Gilead's field teams.[42] Additionally, the Senior Vice President for the North American Commercial Organization sent out periodic updates regarding rules governing Gilead's speaker programs.[43]

Gilead management communicated to all employees that compliance is the responsibility of each individual employee. As part of Gilead's compliance program, employees are advised of several means by which employees can communicate concerns related to compliance. Employees may report violations by contacting their manager, any member of management, or the Human Resources, Legal, or Business Conduct teams, or by using Gilead's online portal or its 24-hour ethics hotline.[44]

Gilead's 24-hour ethics hotline is well-advertised to all employees including through policy documents, regular training, and various other communications. The ethics hotline allows employees to submit reports anonymously.[45] Gilead has a strong and well-advertised non-retaliation policy: "Gilead will not tolerate any form of intimidation or retaliation by any officer, employee, contractor, subcontractor or agent of Gilead against any Employee because of any good faith act taken by the Employee under this policy."[46] The BCM encourages employees to report complaints and ensures that if they do so, their complaints will be shared only on a "need to know" basis, and complainants will be protected from retaliation.

e. *Monitoring and Auditing*

Gilead regularly monitors and audits its business units for compliance with Gilead policies and relevant laws and regulations.[47] Gilead conducts regular internal audits and external audits by third parties. Gilead also engages an independent third-party to monitor its speaker programs through live, in-person event monitoring.[48] Gilead also uses a data analytics dashboard to monitor compliance with Business Conduct guidance.[49]

---

[41] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 22:12-24 (describing the "day-to-day function" of Gilead's Business Conduct attorneys, including responding to questions from the business and provided advice through an email or phone call).
[42] Gilead_Purcell_00201020.
[43] Gilead_Purcell_00116569.
[44] 2013 Business Conduct Manual at 3 (Gilead_Purcell_00000011) ("Questions concerning any policy in this Manual may be addressed to the inquired Gilead employee's manager or the Business Conduct Department. Every Gilead employee or agent who suspects a violation of these policies or the law of other wrongdoing must report the suspected violation…."); at 135 (Gilead_Purcell_00000158) ("Under the Policy, Employees are required to report credible suspicions of [serious wrongdoing within the Company] to their management, the Legal Department, or the Ethics Committee….").
[45] *Id.* at 3 (Gilead_Purcell_00000011).
[46] *Id.* at 136 (Gilead_Purcell_00000159).
[47] *Id.* at 132 (Gilead_Purcell_00000154).
[48] Gilead_Purcell_00006201 (number of HBV programs monitored by external third party "Polaris Management Partners" from 2013-2019); *see, e.g.*, Gilead_Purcell_00200291 (speaker program monitoring "FAQs" shared with the commercial team in 2013).
[49] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 131:25-133:7.

Findings from auditing and monitoring activities are carefully considered by the Business Conduct team and commercial leadership. Monitoring and auditing findings are used to continuously improve and enhance the company's controls, where findings are broadly applicable across the Company.[50]

The Business Conduct unit and other in-house counsel monitor industry developments and OIG guidance to identify and address emerging risk areas. Business Conduct performs quarterly business reviews that analyze compliance with speaker program and advisory board policies.[51]

f. *Enforcement and Discipline*

Gilead has clear investigations and disciplinary guidelines.[52] The company screens new employees to ensure they have not previously been excluded from federal health care programs. Gilead's policies require its employees to promptly report any potential violations of laws, regulations, or company policies and lays out the appropriate procedures for doing so. Gilead convenes Remedial Action Committees—composed of senior-level management from the business, Human Resources, and Legal—to take responsibility for serious disciplinary action decisions resulting from investigations.[53]

Gilead responds promptly to detected offenses and moves swiftly to undertake corrective action where appropriate. The company takes appropriate disciplinary action against employees who violate its compliance policies or applicable laws and regulations, including through coaching, written warnings, suspension, loss of incentive compensation payments, and – where appropriate – termination.[54]

Suspected compliance violations are thoroughly investigated by the appropriate department using appropriate resources.[55] Gilead's General Counsel and members of the Senior Risk Committee are responsible for implementing and enforcing complaint and investigation policies.[56]

---

[50] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 133:12-134:25; Jay Cummings Deposition Transcript at 50:20-51:9.

[51] David Johnson Deposition Transcript at 134:17-136:1; 143:14-144:9.

[52] *See generally* Internal Investigations and Disciplinary Policy (Gilead_Purcell_00278687-91). Prior to the implementation of the Internal Investigations and Disciplinary Policy, Gilead convened similar stakeholders for disciplinary action decisions. Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 59:12-21.

[53] Internal Investigations and Disciplinary Policy (Gilead_Purcell_00278687-94) at 4 (Gilead_Purcell_00278690); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 59:12-21.

[54] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 49:9-51:14 (noting that, "if a concern was raised, Gilead would take that seriously," and describing the investigative process); Gilead_Purcell_00028916 (written warning letter issued to employee after determining the employee failed to properly report all reportable speaker programs HCPs and failed to ensure the accuracy and completeness of program sign-in sheets); Gilead_Purcell_00311270; Gilead_Purcell_00134576 (written notice to former employee who reported purported compliance violations, indicating that Gilead carefully investigated the allegations).

[55] Internal Investigations and Disciplinary Policy (Gilead_Purcell_00278687-91) at 3-4 (Gilead_Purcell_00278689-90); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 49:9-51:14.

[56] 2017 Business Conduct Manual at 156 (Gilead_Purcell_00000801). Prior to 2017, an Ethics Committee was responsible for implementing and enforcing complaint and investigation policies.

g. *Corrective Action*

Gilead's Business Conduct department performs quarterly business reviews that analyze compliance with Advisory Board and Speaker Program policies.[57] Gilead has appropriately and thoroughly investigated identified instances of non-compliance.[58] Gilead appropriately considers factors such as intent, materiality, and cooperation when determining appropriate disciplinary action.[59]

V. GILEAD'S SPEAKER PROGRAMS

I understand that Relators' allegations focus on the propriety of Gilead's Speaker Programs. These programs are one of the areas that Gilead's compliance policies and control environment specifically address. Through its Speaker Bureau, Gilead retains qualified HCPs to speak on Gilead's behalf concerning its products and the diseases that they treat. Gilead utilizes speaker programs to educate members of the healthcare community and those in affected communities about a drug or disease state relevant to Gilead's research or products. Speaker programs serve both educational and promotional purposes.

Speaker programs potentially implicate the AKS because of the risk that they may be perceived to provide monetary benefits to reward prescribers or to induce physicians to prescribe certain products. Accordingly, the areas of compliance concern with such programs are:

- Speaker selection – who is involved in selecting speakers and the criteria used when selecting speakers;
- Speaker payment – how much the speakers receive and whether the compensation reflects fair market value for the time and effort;
- Speaker performance – whether the speaker actually performs the services for which they are contracted;
- Attendee selection – whether the attendees are appropriate for the subject matter and are sufficient in number to make the program worthwhile;
- Venue and menu – whether the venue and menu are appropriate and reasonable so as not to suggest the purpose is to reward the attendees.

Gilead's compliance policies sufficiently address each of the identified risk areas for such programs. Gilead's compliance controls for speaker programs met or exceeded applicable standards.

[57] David Johnson Deposition Transcript at 134:17-136:16.
[58] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 91:3-11.
[59] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 54:3-22; Internal Investigations and Disciplinary Policy (Gilead_Purcell_00278687-91) at 4 (Gilead_Purcell_00278690); 2013 Business Conduct Manual at 4 (Gilead_Purcell_00000012).

The number of speakers in Gilead's Speaker Bureau is based on business need.[60] Gilead prepares an annual needs assessment to determine the number of speakers it will need in a given year.[61] Business Conduct reviews and approves that assessed business need.[62]

Speakers are typically suggested for nomination to the bureau by sales managers. Nominations are reviewed by the Medical Affairs, Marketing, and Business Conduct teams and evaluated on specific criteria including clinical expertise, expertise with Gilead products, and public speaking skills.[63] Potential speakers must be licensed HCPs with no history of OIG or FDA penalties.[64] Medical Affairs personnel review nominations to the Speaker Bureau and ensure that the nominated HCPs exhibit the appropriate clinical background for understanding and educating on Gilead's products or therapeutic areas.[65] In a representative email exchange, the Associate Director for Medical Affairs pushed back on a sales director's nomination where the Medical Affairs personnel thought that the nominee did not have enough post-residency dedicated Hepatitis B experience to warrant inclusion in Gilead's Speaker Bureau.[66] The Speaker nomination and review process is rigorous, and not all nominated speakers are ultimately appointed to the bureau.[67] Speakers must not be selected based on any desire that they prescribe Gilead products as a result of participating in the Speaker Bureau.[68]

Gilead's speakers entered into contractual agreements prior to participating in Gilead's Speaker Bureau.[69] They were required to present an average of at least one speaker program for every six months of a contract year.[70]

Gilead prohibits selecting speakers or determining their compensation with an intent to induce or reward prescription writing.[71] Gilead has a process in place to ensure speaker payments were uniform and reflected fair market value. Gilead utilizes an independent third-party consultant

---

[60] 2013 Business Conduct Manual at 54, 62 (Gilead_Purcell_00000067, 76); Jeremy Schmalzle Deposition Transcript at 86:20-89:15.

[61] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 182:10-184:20 (describing the implementation of the annual needs assessment process, through annual "Brand Plans of Action" and "Requests for Approval"); *see, e.g.*, Gilead_Purcell_00216625 at slide 34.

[62] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 184:12-20 (specifying that a Business Conduct attorney would pre-approve the needs assessment).

[63] 2018 Business Conduct Manual at 66 (Gilead_Purcell_00000941). Leilani Larson Deposition Transcript at 192:16-193:10 (describing the speaker nomination process); Jay Cummings Deposition Transcript at 63:2-25 (same).

[64] 2013 Business Conduct Manual at 62 (Gilead_Purcell_00000076).

[65] *Id.* at 62 (Gilead_Purcell_00000076); Ivan Tai Deposition Transcript at 39:8-40:1.

[66] Gilead_Purcell_00284028.

[67] *Id.*

[68] 2013 Business Conduct Manual at 2 (Gilead_Purcell_00000010) ("Gilead Personnel may not provide anything of value—including, but not limited to, consulting fees, compensation, grants, or gifts—to induce a healthcare professional or healthcare entity to purchase, prescribe, use, or recommend a Gilead product."), at 73 (Gilead_Purcell_00000089) (Speaker compensation may not be "intended to induce or reward the prescription of Gilead products"); Jay Cummings Deposition Transcript at 233:2-17 (describing the speaker nomination process).

[69] 2013 Business Conduct Manual at 62 (Gilead_Purcell_00000076).

[70] 2015 Business Conduct Manual at 58 (Gilead_Purcell_00000550). Prior to 2015, speakers were required to present at least two speaker programs per contract year. 2013 Business Conduct Manual at 60 (Gilead_Purcell_00000074).

[71] 2013 Business Conduct Manual at 2 (Gilead_Purcell_00000010) ("Gilead Personnel may not provide anything of value—including, but not limited to, consulting fees, compensation, grants, or gifts—to induce a healthcare professional or healthcare entity to purchase, prescribe, use, or recommend a Gilead product."), at 73 (Gilead_Purcell_00000089) (Speaker compensation may not be "intended to induce or reward the prescription of Gilead products"); Jay Cummings Deposition Transcript at 233:2-17 (describing the speaker nomination process).

to define fair market value for speaker payments, which are established in advance and take into consideration national compensation survey data.[72] Total compensation to an HCP on Gilead's Speaker Bureau in connection with speaker training and speaker programs was subject to an annual cap of $100,000 across all therapeutic areas.[73] Exceptions must be based on a compelling business need, and all requests for exceptions are individually reviewed and approved by Business Conduct.[74] Gilead may reimburse HCP-speakers only for reasonable expenses related to travel, lodging, and meals incurred in connection with speaker programs.[75] Speakers are compensated for actual time spent in, preparing for, and travelling to training and speaker programs, except that speakers are compensated for engagements cancelled at the last minute only when the cancellation is not attributable to the speaker; payment for time and expenses incurred may be made subject to review and consideration by Business Conduct.[76] Gilead utilizes Centris—a third-party system—to track speaker compensation. The business has automated controls in place to be alerted when speakers near or reach the $100,000 compensation cap.[77] Moreover, Centris implements a control whereby the user is prohibited from moving forward in the system when the system detects that the speaker's compensation has met the cap.[78]

Speakers are trained through live, in-person programs at least annually, including on compliance.[79] Gilead regularly evaluates its speaker training and education programs – including by soliciting feedback from the speaker attendees – to ensure that its training adequately conveys the relevant disease and product information, laws, and regulations affecting speaker events, and Gilead's Business Conduct policies.[80]

Gilead engages a third-party vendor—Advanced Health Media, LLC ("AHM")—to operationalize its speaker program logistics.[81] Speakers are required to use only Gilead-approved materials during their presentation.[82] In its contracts with speakers and at speaker trainings, Gilead

---

[72] 2013 Business Conduct Manual at 55, 73-74 (Gilead_Purcell_00000068, 88-89). *See, e.g.*, Gilead_Purcell_00132634 (Gilead's HBV OLP rate card prior to implementation of the Fair Market Value calculator); Gilead_Purcell_00206173-209 (Gilead's Fair Market Value calculator training, describing the principles underlying the Fair Market Value calculation and the use of Gilead's calculator).

[73] 2013 Business Conduct Manual at 74 (Gilead_Purcell_00000089). From 2013-2015, the $100,000 total compensation cap included all fees paid to HCPs including for consulting and advisory services. In 2016, the cap was clarified to include only fees paid for speaker programs and speaker training. The cap does not include reimbursement for travel expenses. All meal expenses for any HCP are capped at $2,000 annually. 2013 Business Conduct Manual at 32 (Gilead_Purcell_00000043).

[74] Gilead_Purcell_00000802. From 2015 through 2016, speaker compensation could exceed $100,000 only with a written exception granted by the North America Compliance Review Committee. 2015 Business Conduct Manual at 54 (Gilead_Purcell_00000546).

[75] 2013 Business Conduct Manual at 64 (Gilead_Purcell_00000078).

[76] 2013 Business Conduct Manual at 74 (Gilead_Purcell_00000089).

[77] AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 131:10-23 ("[T]he system will stop the program from being submitted if a speaker has reached his or her annual cap."); Gilead_Purcell_00290431 (indicating that a "reserve" is withheld below the $100,000 cap).

[78] AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 131:10-23 ("The system will stop the program from being submitted if a speaker has reached his or her annual cap."); Gilead_Purcell_00290431.

[79] 2013 Business Conduct Manual at 60 (Gilead_Purcell_00000074); *see, e.g.*, Gilead_Purcell_00308613 (in-person, annual training); Gilead_Purcell_00103532 (speaker training webcast to address Viread label update).

[80] REL_000845 (summary of 2014 Speaker Education meeting attendee evaluations).

[81] 2013 Business Conduct Manual at 68 (Gilead_Purcell_00000083). AHM was acquired by IQVIA in 2018.

[82] 2013 Business Conduct Manual at 71 (Gilead_Purcell_00000086); IQV-Gilead-000060 (speaker program live-monitoring checklist, including the following check by the external monitor: "Did the speaker use a current, approved

emphasizes its requirements to use only current, Gilead-approved speaker slides and to present the entire slide deck without modification.[83] All presentation materials are approved by Gilead personnel—including Business Conduct—to ensure they include information on safety and efficacy, are truthful and non-misleading, identify Gilead as the event sponsor, and exclude any unapproved comparative claims regarding competing products.[84]

Gilead prohibits the use of inappropriate venues and lavish meals for speaker trainings and programs.[85] Gilead requires that the venue be conducive to the educational nature of the meeting, and that it permits the audience to clearly view and hear the speaker and any presentation materials.[86] Venues are selected based on proximity to attendees, transportation, quality and cost of meeting rooms and business support, and other business-related factors.[87] Hotel accommodations may not be rated higher than four stars and may not be a resort.[88] Gilead strictly enforces its $125 per person meal cap for speaker program meals, which includes tax and tip.[89] The Business Conduct team alerts Sales personnel when speaker program meals exceed approved meal limits, requesting that managers provide appropriate coaching to emphasize Gilead's meal limits and including additional guidance regarding speaker program meals.[90] In some instances, Gilead added venues where meals exceeded approved limits to its "Do Not Use" list.[91]

Gilead policies require at least four confirmed attendees at least 48 hours in advance of a program.[92] All attendees must be appropriate for the program.[93] Attendees are appropriate for branded professional programs if they are within the continuum of care for HBV patients and can benefit from being informed about the nature of treatment for the HBV disease state.[94] If speaker programs were conducted with fewer than four attendees present, Gilead's speaker programs logistics vendor notified Sales and Commercial leadership, and the TS responsible for the event

---

Gilead slide deck?"); IQV-Gilead-000034 (training for speaker program live-monitors, including that the speaker may only use "current Gilead-approve speaker slides and materials").

[83] *See, e.g.,* Gilead_Purcell_00006447 at *125; Gilead_Purcell_00127845 at *9; IQV-Gilead-000060.

[84] 2013 Business Conduct Manual at 71 (Gilead_Purcell_00000086); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 14:11-18; Jeremy Schmalzle Deposition Transcript at 30:12-22.

[85] 2013 Business Conduct Manual at 65 (Gilead_Purcell_00000079); AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 121:2-122:10; 123:16-124:6.

[86] 2013 Business Conduct Manual at 65 (Gilead_Purcell_00000079). *See, e.g.,* Gilead_Purcell_00132589 at *26 (Business Conduct training requiring Speaker Program venues to be conducive to educational discussion); IQV-Gilead-000060 (speaker program live-monitoring checklist, including the following checks by the external monitor: "Was the venue conducive to a business discussion (private, not too loud, etc.)?" and "Please describe the venue setting (private room, separate or defined setting, other).").

[87] 2013 Business Conduct Manual at 65 (Gilead_Purcell_00000079); Ivan Tai Deposition Transcript at 88:6-23.

[88] 2013 Business Conduct Manual at 65 (Gilead_Purcell_00000079).

[89] 2013 Business Conduct Manual at 34 (Gilead_Purcell_00000045); Leilani Larson Deposition Transcript at 91:9-15.

[90] *See, e.g.,*Gilead_Purcell_00317271; Gilead_Purcell_00315141.

[91] *See, e.g.,*Gilead_Purcell_00317271; AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 121:2-123:11 (describing a list of venues that may not be used for Gilead speaker programs, and describing the process AHM undertook to ensure that these venues were not used).

[92] 2013 Business Conduct Manual at 70 (Gilead_Purcell_00000085).

[93] 2013 Business Conduct Manual at 70 (Gilead_Purcell_00000085); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 155:19-156:7.

[94] 2013 Business Conduct Manual at 70 (Gilead_Purcell_00000085); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 155:19-156:7.

was required to submit an explanation of why fewer than four attendees were present.[95] Guests of attendees may not attend speaker programs unless they are themselves within the relevant continuum of care.[96] One Director of Marketing testified that of the 70 – 80 speaker programs he attended while working at Gilead, he never witnessed any attendees without a connection to a medical practice.[97] Speaker program attendees may attend a maximum of three programs addressing the same topic, and a maximum of ten programs per calendar year regardless of topic.[98] Gilead implemented automated controls through its speaker program logistics vendor to ensure compliance with these rules.[99] For example, Centris dispenses an error message if an invitee has reached the three-program limit on the topic being presented *prior* to invitations being sent; the event cannot be scheduled without removing the participant who has reached the cap.[100]

HCPs on the Speaker Bureau are prohibited from attending any programs on topics for which they are certified to present.[101] In addition to the centralized database Gilead uses to track attendance and compensation related to speaker events,[102] the Business Conduct team sends notices to Sales personnel when an HCP within their territory reaches the attendance cap.[103] Business Conduct underscores to the Sales team that even if the HCP may come to a program by way of a broader invitation not directed to that particular HCP, that HCP will still be turned away at the door from an additional speaker program on that topic.[104]

Gilead regularly monitors and audits its speaker programs, using both Business Conduct personnel, management, and external monitors and auditors.[105] Internally, Sales and Marketing personnel track speaker utilization metrics to ensure that speakers meet the presentation

---

[95] 2013 Business Conduct Manual at 70 (Gilead_Purcell_00000085); *e.g.*, Gilead_Purcell_00271692 (email notification from third-party logistics provider regarding a program conducted with fewer than four attendees, including follow-up email between Regional Director and Senior Regional Director); Gilead_Purcell_00200945 (same); AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 115:6-14.

[96] 2013 Business Conduct Manual at 70 (Gilead_Purcell_00000085). As of 2018, spouses and other guests of a speaker may not attend a speaker program, even if that person was within the continuum of care. 2018 Business Conduct Manual at 76 (Gilead_Purcell_00000951).

[97] Ilija Zlatar Deposition Transcript at 211:7-211:24.

[98] This rule has evolved during the Relevant Period. Starting in 2016, attendees were limited to three programs per topic per calendar year. 2016 Business Conduct Manual at 68 (Gilead_Purcell_00000404). In 2017, Gilead updated this rule to three programs per topic per lifetime of the topic, and a maximum of 10 programs per calendar year regardless of topic. Gilead_Purcell_00116569 (email communication from Gilead's then-Chief Commercial Officer to the commercial team regarding the rule adjustments); 2018 Business Conduct Manual at 76 (Gilead_Purcell_00000951).

[99] AHM Corporate Designee (Jane Avalos) Deposition Rough Transcript at 116:25-117:24 ("Systematically it does – there is a process in place prior to the day of the program for the system to prevent that attendee to be added [to the program] into the system."); Purcell_00275523 (*with* Gilead_Purcell_00275529).

[100] Gilead_Purcell_00275599 at *17-18.

[101] As of 2016, an HCP on the Speaker Bureau could attend up to two programs per year on a topic for which they were certified to present. 2016 Business Conduct Manual at 68 (Gilead_Purcell_00000404). In 2018, Gilead updated this rule so that an HCP on the Speaker Bureau could not attend any programs on topics for which they were certified to present unless approved by Business Conduct. 2018 Business Conduct Manual at 76 (Gilead_Purcell_00000951). The Business Conduct Manual allows for an exception to be made pursuant to Sales Management and Business Conduct approval. *Id.*

[102] Gilead_Purcell_00281003 at slides 4-5; Gilead_Purcell_00272572.

[103] *See, e.g.*, Gilead_Purcell_00332474; Gilead_Purcell_00332124; Gilead_Purcell_00332449.

[104] *Id.*

[105] Jeremy Schmalzle Deposition Transcript at 156:16-157:17.

completion requirements included within the speaker's contract.[106] Managers—including upper-level management—also regularly attend speaker programs hosted by their sales representatives. Externally, third-party monitors attend certain speaker programs selected for monitoring, often with very short or even no notice provided to the program hosts that the program will be monitored.[107]

For externally monitored events, Gilead's Business Conduct team identified the percentage and type of programs to be monitored using a risk-based approach.[108] The external monitor would arrive to selected events and observe the program. One TS stated that he would be alerted only five minutes prior to the start of a program that the program was to be monitored.[109] The monitor would then conduct a review of more than 25 elements of the program, including related to the venue, meal, presentation content and quality, on-label marketing topics, and attendees.[110] During the Relevant Period, Gilead formally monitored 52 speaker programs within the Hepatitis B franchise, on both announced and unannounced bases.[111]

Gilead also conducted an audit of its speaker programs during the Relevant Period to identify inadequacies and potential improvements to its compliance program.[112] Gilead incorporated the findings from this audit to enhance speaker program implementation controls and consistency across the company.

During the Relevant Period, Gilead management received contemporaneous and automated notifications when speaker program policies were not fully complied with and regularly followed up with the TS involved, evaluating his or her explanation and the context for the non-compliance and providing coaching or other follow-up as appropriate.[113] Gilead also incorporated findings from its speaker program monitoring into improvements to its speaker programs.[114] As an example, the Marketing team added a slide to speaker program slide decks, disclosing Gilead's sponsorship of the program and that the Speaker was paid by Gilead as a result of findings from Business Conduct's monitoring program.[115]

When appropriate, failure to comply with company policies resulted in adverse actions. Speakers who violated Gilead's compliance policies were removed from the Speaker Bureau.[116]

---

[106] REL_000393 at 9.
[107] David Johnson Deposition Transcript at 148:17-150:7.
[108] Gilead_Purcell_00013751 (reflecting meeting between HBV Marketing and third-party monitor to discuss "HBV product-specific" information ahead of the monitoring project); Gilead_Purcell_00013801 (same); Gilead_Purcell_00208886 (same).
[109] Ivan Tai Deposition Transcript at 176:7-177:3, 178:9-14.
[110] *See*, e.g., Gilead_Purcell_00212691 (with Gilead_Purcell_00212695) (kick-off document describing the annual Speaker Program Monitoring project); IQV-Gilead-000060 (speaker program live-monitoring checklist).
[111] Gilead_Purcell_00006201.
[112] Gilead_Purcell_00340625.
[113] *See, e.g.*, Gilead_Purcell_00271692; Gilead_Purcell_00200945; Gilead_Purcell_00317271; Gilead_Purcell_00315141.
[114] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 126:12-127:4 (describing how findings from ad board monitoring could lead to updated guidance and/or training).
[115] *See, e.g.,* Gilead_Purcell_00032932.
[116] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 29, 2021 at 51:5-14 (explaining that speakers may be removed from the bureau because of compliance concerns); 2013 Business Conduct Manual at 73 (Gilead_Purcell_00000088).

a. *OIG Guidance*

At all times during the Relevant Period, the design and operation of Gilead's speaker programs satisfied applicable OIG guidance regarding speaker arrangements. Gilead's policies *exceeded* the recommendations set out in the OIG CPG for Pharmaceutical Manufacturers.

At all times during the Relevant Period, Gilead's speaker arrangements satisfied all of the Safe Harbor conditions other than the requirements that: (i) contracts for part time services had to specify the exact schedule of when the services would be provided; and (ii) the total aggregate compensation under the contract had to be specified in advance.[117] While Gilead's agreements with HCPs did not specify the precise length of the speaker programs (and therefore did not specify the exact length of time for which the services would be provided to Gilead), at all times during the Relevant Period Gilead's speaker arrangements complied with the current safe harbor for personal services arrangements and would have been fully protected under the AKS. In my experience and opinion, it is very unlikely that an arrangement that satisfies a safe harbor today would have ever violated the AKS.

Government and industry guidance regarding speaker programs continue to evolve. In my experience and opinion, Gilead has supplied best efforts to meet this evolving guidance in its policies and to live up to the government's expectations in practice.

b. *PhRMA Code*

Gilead's speaker arrangements and policies complied with the PhRMA Code. While Gilead did not become a member of PhRMA until January 2019, it nonetheless voluntarily followed the PhRMA Code throughout the Relevant Period. At all times during the Relevant Period, Gilead's speaker arrangements and policies incorporated the controls set out in the PhRMA Code.

c. *CIAs*

Gilead's policies generally met stringent standards of CIA requirements for speaker programs. Although not required, Gilead's speaker arrangements and policies during the Relevant Period also substantially mirrored the speaker program requirements that the OIG was imposing on pharmaceutical companies settling False Claims Act litigation.

At all times during the Relevant Period, Gilead had policies and systems in place to track its speaker program contracting, payments, and venues. Sales personnel were required to and did file and close out reports on each speaking engagement, including any compliance problems. Gilead also utilized independent outside monitors to audit an appropriately representative number of its speaker programs.

VI. Gilead's Advisory Boards

Gilead engages HCPs to advise the company on various scientific and commercial topics and solicit their feedback on relevant drugs and disease states.[118] Gilead engages these advisors to provide advice related to product development and scientific, marketing, and promotional strategies and materials – which Gilead uses to advance the company's operations. Gilead

[117] *See, e.g.*, Gilead_Purcell_00319575; Gilead_Purcell_00247920.

[118] 2013 Business Conduct Manual at 49 (Gilead_Purcell_00000062); *see, e.g.*, Gilead_Purcell_00018798 (Gilead Advisory Board Request for Approval describing the "primary objectives" of the proposed 2016 Post-AASLD advisory meeting).

conducts advisory boards only pursuant to legitimate business needs.[119] The insights obtained through advisory boards are synthesized into Executive Summaries and used to inform the marketing program.[120] Gilead personnel may not and do not conduct Return on Investment or similar analyses on advisory boards or advisory board participants.[121] Gilead strictly prohibits the use of advisory boards as promotional or to induce or reward prescription writing.[122]

Gilead's Business Conduct attorneys pre-approve advisory boards based on a detailed written Request for Approval ("RFA") "that clearly identifies the legitimate business need for the meeting, objectives, invitee details, criteria for selecting participants, Gilead attendees, proposed compensation, topics to be covered, agenda, location, and any other pertinent information."[123]

The Marketing department is ultimately responsible for determining appropriate HCPs to invite to an Advisory Board.[124] Advisors for some commercial advisory boards were nominated by Senior Regional Directors for selection by the Marketing Department.[125] Advisory board participants were selected based on their treatment expertise and other relevant factors such as research and publication experience, level of product knowledge, and more.[126] Gilead strictly prohibits selecting speakers or advisors to incentivize or reward prescription writing.[127] Advisors who provided little or no feedback should not be invited to attend future meetings.[128]

All advisors and consultants must enter into a written contractual agreement before participating in advisory board meetings.[129] Gilead compensates HCPs at fair market value for their participation in advisory boards.[130] Advisor compensation is determined by Business Conduct using a Fair Market Value calculator.[131] Gilead may reimburse HCPs only for reasonable travel and related expenses incurred in connection with advisory boards.[132]

---

[119] 2013 Business Conduct Manual at 50 (Gilead_Purcell_00000063).
[120] *E.g.*, Gilead_Purcell_00006709 (2013 Enhancing Awareness of Issues in Hepatis B Management advisory board executive summary, including learnings and recommendations).
[121] 2013 Business Conduct Manual at 50 (Gilead_Purcell_00000063); David Johnson Deposition Transcript at 238:20-24.
[122] 2013 Business Conduct Manual at 49 (Gilead_Purcell_00000062) ("Neither Advisory Meetings nor consulting arrangements may be used as educational opportunities, promotional tools, or to reward or induce the prescription, use, or recommendation of Gilead products.").
[123] 2017 Business Conduct Manual at 55 (Gilead_Purcell_00000700); *see, e.g.*, Gilead_Purcell_00018798 (Gilead Advisory Meeting Request for Approval, as approved by Business Conduct and the HBV Commercial leader); Gilead_Purcell_00007801 (same); Gilead_Purcell_00007840 (same); Gilead_Purcell_00007854 (same). As of 2017, only Sales employees at the Senior Regional Director level or above are eligible to submit an RFA. 2017 Business Conduct Manual at 50 (Gilead_Purcell_00000695).
[124] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 121:7-14.
[125] Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 119:19-122:1.
[126] 2013 Business Conduct Manual at 53 (Gilead_Purcell_00000066); Gilead Corporate Designee (Erica Chien) Deposition Rough Transcript Apr. 30, 2021 at 55:2-11.
[127] 2013 Business Conduct Manual at 49 (Gilead_Purcell_00000062); Jeremy Schmalzle Deposition Transcript at 223:15:224:8.
[128] 2013 Business Conduct Manual at 52 (Gilead_Purcell_00000065).
[129] 2013 Business Conduct Manual at 54 (Gilead_Purcell_00000067).
[130] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068); Gilead_Purcell_00007886 (Advisory Board Meeting RFA incorporating Fair Market Value rates).
[131] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068); Gilead_Purcell_00000802 (FMV Calculator Training).
[132] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068).

Venues for advisory boards—similar to speaker programs—must be conducive to business meetings.[133] It is improper to select venues "based upon the existence or quality of amenities such as golf courses and spas."[134] Instead, venue selection should be based on whether a locale has the accessibility and facilities necessary to host a business meeting, and may not be held at lavish locations.[135]

Gilead personnel—which may include Legal—attend and monitor advisory boards.[136] During the Relevant Period, Gilead conducted an internal audit focused on advisory board meetings, which evaluated the controls in place to ensure that RFAs were appropriately approved; advisors were properly selected; compensation to advisors was consistent with fair market value; and other aspects of advisory boards were in compliance with company policies.[137]

Gilead's compliance policies and controls for advisory boards met the then-current applicable government and industry guidance. At all times during the Relevant Period, Gilead's consulting agreements satisfied all of the Safe Harbor conditions other than the requirements that: (i) contracts for part time services had to specify the exact schedule of when the services would be provided; and (ii) the total aggregate compensation under the contract had to be specified in advance.[138] No arrangements for services on an "as-needed" basis—such as Gilead's requirement that HCPs be available periodically after advisory boards for follow-up consultation—could satisfy the Safe Harbor. While Gilead's agreements with HCPs did not specify the precise length of the advisory boards (and therefore did not specify the exact length of time for which the services would be provided to Gilead), at all times during the Relevant Period Gilead's consulting arrangements complied with the current safe harbor for personal services arrangements and would have been fully protected under the AKS. In my experience and opinion, it is very unlikely that an arrangement that satisfies a safe harbor today would have ever violated the AKS. Gilead's controls for its advisory boards were very similar to the speaker program policies in terms of selection, compensation, and venue. The policies were designed to ensure that the advisory boards provided useful information for Gilead, and that the attendees were qualified, reasonable in number, and compensated based on fair market value.

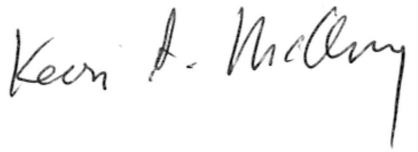
VII. Conclusion

Based upon my experience and my review of the documents listed in Appendix C, I offer the following opinions:

- Gilead has an appropriately-sized and well-resourced compliance department.
- Gilead has an effective overall compliance program that is consistent with and conforms to industry and government guidance.
- Gilead's compliance policies and controls for speaker programs met or exceeded applicable standards.

[133] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068).
[134] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068).
[135] 2013 Business Conduct Manual at 55 (Gilead_Purcell_00000068).
[136] David Johnson Deposition Transcript at 144:14-145:5.
[137] Gilead_Purcell_00340638.
[138] *See, e.g.*, Gilead_Purcell_00319575; Gilead_Purcell_00122920; Gilead_Purcell_00247920.

- Gilead's compliance policies and controls for advisory board programs met or exceeded applicable standards.
- Occasional failures to comply with controls are unavoidable, even with a state-of-the-art compliance program, and do not render the compliance program ineffective. Federal regulators would not likely view such occasional violations of voluntary guidance as actionable.



May 3, 2021

Kevin G. McAnaney, Esq.

Appendix A

KEVIN G. MCANANEY
7203 Denton Road
Bethesda, MD 20814
(240) 620-5449

2003 – Present

LAW OFFICES OF KEVIN G. MCANANEY

Established boutique health care law practice, focusing on the regulation of fraud and abuse.

1997 - 2003

CHIEF, INDUSTRY GUIDANCE BRANCH
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
Washington, D.C.

Joined government after fourteen years in private law practice to set up new IG function to coordinate and issue guidance to the health care industry related to health care fraud and abuse, including advisory opinions, special fraud alerts, and regulatory "safe harbors" to the federal anti-kickback statute. Recruited and supervised four experienced health care lawyers from private sector. Worked closely with HCFA (now CMS) and Department of Justice in developing and issuing guidance through advisory opinions, special fraud alerts, informal letters and rulemaking. Developed final rule implementing the Ethics in Patient Referrals Act (also known as "Stark II"), published January 2001. Worked closely with DOJ on criminal and civil prosecutions involving the anti-kickback statute and other fraud and abuse laws. Frequent speaker at industry conferences.

1986 -1997

PARTNER, DEWEY BALLANTINE
Washington, D.C.

Developed general regulatory and transactional practice in the health care, food and drug, and environmental areas. Represented various clients, including physicians, medical device and pharmaceutical manufacturers, hospital and health care companies, health care trade associations and investment companies underwriting health care companies' public offerings. Developed and headed firm's environmental practice, primarily in Superfund litigation. Worked closely with Joseph Califano, the former Secretary of the Department of Health, Education and Welfare, and head of the firm's Washington, D.C. office.

1983 - 1986

ASSOCIATE, DEWEY BALLANTINE
Washington, D.C.

Worked as associate on various regulatory and transactional matters in the health care, food and drug, and environmental areas.

1981 - 1983

ASSISTANT COUNSEL TO GOVERNOR HUGH CAREY
Albany, New York

Responsible for developing, coordinating and negotiating the Governor's legislative program in the health and human services areas, including the passage of legislation establishing the nation's first all payer hospital prospective payment system and securing waiver from the U.S. Department of Health, Education and Welfare to include Medicare and Medicaid participation in the reimbursement system. Responsible for coordinating the legislative programs of the State's health and human services agencies. Represented and advised the Governor with respect to other legislation in the health and human services areas. Coordinated activities of State health and human services agencies that affected more than one agency. Developed proposal that resulted in creation of the Governor's Task Force on Life and the Law, a panel consisting of industry, religious and political leaders to develop consensus on medico-legal issues, such as withdrawal of treatment and the definition of death.

1980 - 1981

ASSOCIATE, KELLEY DRYE & WARREN
Director of Legal Affairs, The New York Hospital
New York, New York

Staffed the Office of Legal Affairs for The New York Hospital, one of the largest teaching hospitals in the country. Responsible for the initial intake, evaluation and coordination of all legal matters affecting the Hospital on a daily basis. Provided general advice relating to medical malpractice, medical staff relations, informed consent, State regulatory matters, and other miscellaneous legal issues.

1977 - 1980

ASSOCIATE, KELLEY DRYE & WARREN
New York, New York

Litigation Associate. Researched and drafted legal memoranda, briefs and pleadings.

EDUCATION: Phillips Exeter Academy (diploma, 1967)
B.A., University of North Carolina at Chapel Hill, 1971
J.D., Columbia University School of Law, 1977

Appendix B

KEVIN McANANEY

EXPERT WITNESS TESTIMONIAL/DEPOSITION EXPERIENCE
(Previous Four Years)

1. *Comprehensive Neurosurgical, PC et al v. The Valley Hospital et al*, Civil action No. BER-L-6794-16 in the Superior Court Of New Jersey, Law Division, Bergen County; deposition
2. *US ex rel. Derrick v. Roche Diagnostics Corp., et al*., CA. No. 1:14-cv-04601(N.D.IL); deposition
3. *US ex rel Magee v. Heart Hospital of the Southwest, LLP*, Case No. 4-16-cv-00717 (E.D. TX); deposition
4. *Hebrew Homes Health Network, Inc., et al. v. Greenberg Traurig, P.A., et al*, Case No.: CACE-2017-012846-CA-01, Circuit Court of the 11th Judicial Circuit In And For Miami-Dade County, FL; deposition

Appendix C

MATERIALS CONSIDERED

Regulations and Federal Register Publications

- 42 C.F.R. § 1001.952
- 68 Fed. Reg. 23,731 (May 5, 2003)
- 85 Fed. Reg. 77,684 (Dec. 2, 2020)

Case Materials

- Fourth Amended Complaint with Exhibit A, *United States ex rel. Purcell v. Gilead Sciences, Inc.*, No. 2:17-cv-03523-MAK (E.D. Pa. Sept. 30, 2020), ECF No. 117
- Answer of Gilead Sciences, Inc., *United States ex rel. Purcell v. Gilead Sciences, Inc.*, No. 2:17-cv-03523-MAK (E.D. Pa. Oct. 14, 2020), ECF No. 119
- Deposition Transcript of Marc Aquino (Aug. 25, 2020) and Exhibits 1-14
- Deposition Transcript of David Johnson (Aug. 31, 2020) and Exhibits 1-20
- Deposition Transcript of Leilani Larson (Sept. 4, 2020) with Exhibits 1-30
- Deposition Transcript of Jeremy Schmalzle (Sept. 25, 2020) with Exhibits 1-13
- Deposition Transcript of Ilija Zlatar (Nov. 11, 2020) with Exhibits 1-15
- Deposition Transcript of Tana Sarntinoranont (Aug. 27, 2020) with Exhibits 1-10
- Deposition Transcript of Ivan Tai (Oct. 5, 2020) with Exhibits 1-11
- Deposition Transcript of Graham Warden (Sept. 23, 2020) with Exhibits 1-23
- Deposition Transcript of Jay Cummings (Mar. 9, 2021) with Exhibits 1-22
- Deposition Transcript [rough draft] of Kimberly Groome (Apr. 9 and 10, 2021) with Exhibits 1-39
- Deposition Transcript [rough draft] of Calvin Pan (Apr. 22, 2021)
- Deposition Transcript [rough draft] of Chris Purcell (Apr. 22 and 23, 2021)
- Deposition Transcript [rough draft] of AHM (Apr. 28, 2021)
- Deposition Transcript [rough draft] of Erica Chien (April 29 and 30, 2021)

Corporate Integrity Agreements

- Corporate Integrity Agreement between Office of Inspector General of the Department of Health and Human Services and Par Pharm. Cos., Inc. and Par Pharm., Inc., dated March 4, 2013
- Corporate Integrity Agreement between Office of Inspector General of the Department of Health and Human Services and Novartis Corp., dated June 30, 2020
- Corporate Integrity Agreement between Office of Inspector General of the Department of Health and Human Services and Daiichi Sankyo, Inc., date Jan. 7, 2015
- Corporate Integrity Agreement between Office of Inspector General of the Department of Health and Human Services and Shire North American Group, Inc., dated Sept. 15, 2014
- Corporate Integrity Agreement between Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals Inc., dated Feb. 24, 2014
- Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc., dated Aug. 30, 2010

Federal Guidance

- Justice Manual § 9-28.800
- U.S. Department of Justice Criminal Division: Evaluation of Corporate Compliance Program (Updated June 2020)
- U.S. Sentencing Commission 2018 Chapter 8
- OIG: Special Fraud Alert: Speaker Programs (Nov. 16, 2020)
- OIG: Focus on Compliance: The Next Generation of Corporate Integrity Agreements (Oct. 9, 2012)
- OIG: Compliance Program Guidance for Pharmaceutical Manufacturers (Apr. 2003)
- U.S. Sentencing Commission Guideline Manual Annotated 2018 Chapter 8
- U.S Sentencing Commission Guideline Manual: An Overview of the Organizational Guidelines

PhRMA Guidance

- PhRMA Code on Interactions with Healthcare Professionals (Apr. 19, 2002)
- PhRMA Code of Interactions with Healthcare Professionals (July 2008)
- PhRMA: Code on Interactions with Health Care Professionals (Sept. 2009)

Other

- Gilead Sciences, Inc. Code of Ethics (Nov. 4. 2020)
- Gilead Sciences, Inc. Anti-Bribery and Anti-Corruption Policy
- Gilead Sciences, Inc. Board Guidelines (Nov. 4, 2020)
- Gilead Sciences, Inc. Lead Independent Director Charter (Nov. 4, 2020)
- Gilead Sciences, In. Audit Committee Charter (as amended Noc. 3. 2020)

Other Cases

- Order, *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. 2:02-cv-02964-AB (E.D. Pa. Nov. 12, 2020), ECF No. 433
- Order, *United States ex rel. Bilotta v. Novartis Pharms. Corp.*, No. 1:11-cv-00071-PGG (S.D.N.Y. Mar. 31, 2019), ECF No. 296
- Memorandum Decision and Order Denying Defendants' Motion for Summary Judgment, *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 1:13-cv-03702-CM-OTW (S.D.N.Y. Feb. 27, 2019), ECF No. 163
- Deferred Prosecution Agreement for Biomet, Inc.
- Deferred Prosecution Agreement for DePuy Orthopedics, Inc.
- Deferred Prosecution Agreement for Recon and Smith & Nephew, Inc.
- Deferred Prosecution Agreement for Zimmer Holdings, Inc.

Bates-Stamped Documents

- Gilead_Purcell_00327019
- Gilead_Purcell_00000869
- Gilead_Purcell_00000639
- Gilead_Purcell_00000330

- Gilead_Purcell_00000486
- Gilead_Purcell_00000163
- Gilead_Purcell_00000001
- Gilead_Purcell_00003470
- Gilead_Purcell_00003472
- Gilead_Purcell_00055061
- Gilead_Purcell_00132285
- Gilead_Purcell_00147424
- Gilead_Purcell_00147443
- Gilead_Purcell_00162114
- Gilead_Purcell_00166206
- Gilead_Purcell_00166447
- Gilead_Purcell_00166968
- Gilead_Purcell_00167529
- Gilead_Purcell_00168120
- Gilead_Purcell_00180689
- Gilead_Purcell_00189398
- Gilead_Purcell_00189400
- Gilead_Purcell_00189401
- Gilead_Purcell_00193399
- Gilead_Purcell_00200000
- Gilead_Purcell_00200945
- Gilead_Purcell_00253183
- Gilead_Purcell_00270813
- Gilead_Purcell_00270814
- Gilead_Purcell_00270815
- Gilead_Purcell_00270817
- Gilead_Purcell_00271692
- Gilead_Purcell_00271697
- Gilead_Purcell_00296106
- Gilead_Purcell_00311377
- Gilead_Purcell_00311389
- Gilead_Purcell_00311391
- Gilead_Purcell_00311394
- Gilead_Purcell_00311481
- Gilead_Purcell_00311623
- Gilead_Purcell_00312025
- Gilead_Purcell_00312027
- Gilead_Purcell_00315141
- Gilead_Purcell_00315160
- Gilead_Purcell_00317271
- Gilead_Purcell_00317324
- Gilead_Purcell_00317639
- Gilead_Purcell_00317647

- Gilead_Purcell_00317667
- Gilead_Purcell_00317680
- Gilead_Purcell_00318545
- Gilead_Purcell_00318574
- Gilead_Purcell_00319412
- Gilead_Purcell_00321055
- Gilead_Purcell_00321056
- Gilead_Purcell_00321057
- Gilead_Purcell_00321084
- Gilead_Purcell_00321087
- Gilead_Purcell_00325266
- Gilead_Purcell_00325271
- Gilead_Purcell_00325460
- Gilead_Purcell_00325731
- Gilead_Purcell_00325733
- Gilead_Purcell_00325736
- Gilead_Purcell_00325874
- Gilead_Purcell_00325881
- Gilead_Purcell_00326010
- Gilead_Purcell_00329400
- Gilead_Purcell_00330437
- Gilead_Purcell_00332124
- Gilead_Purcell_00332157
- Gilead_Purcell_00332179
- Gilead_Purcell_00332181
- Gilead_Purcell_00332184
- Gilead_Purcell_00332210
- Gilead_Purcell_00332216
- Gilead_Purcell_00332219
- Gilead_Purcell_00332221
- Gilead_Purcell_00332223
- Gilead_Purcell_00332240
- Gilead_Purcell_00332259
- Gilead_Purcell_00332433
- Gilead_Purcell_00332449
- Gilead_Purcell_00332453
- Gilead_Purcell_00332472
- Gilead_Purcell_00332474
- Gilead_Purcell_00332484
- Gilead_Purcell_00332489
- Gilead_Purcell_00332541
- Gilead_Purcell_00332545
- Gilead_Purcell_00332548
- Gilead_Purcell_00332690

- Gilead_Purcell_00332694
- Gilead_Purcell_00332696
- Gilead_Purcell_00332704
- Gilead_Purcell_00332707
- Gilead_Purcell_00332716
- Gilead_Purcell_00332880
- Gilead_Purcell_00332886
- Gilead_Purcell_00332888
- Gilead_Purcell_00332890
- Gilead_Purcell_00332892
- Gilead_Purcell_00332895
- Gilead_Purcell_00332899
- Gilead_Purcell_00332903
- Gilead_Purcell_00332905
- Gilead_Purcell_00332907
- Gilead_Purcell_00332909
- Gilead_Purcell_00332912
- Gilead_Purcell_00332913
- Gilead_Purcell_00332915
- Gilead_Purcell_00332917
- Gilead_Purcell_00332925
- Gilead_Purcell_00332935
- Gilead_Purcell_00332945
- Gilead_Purcell_00332947
- Gilead_Purcell_00332950
- Gilead_Purcell_00332953
- Gilead_Purcell_00332955
- Gilead_Purcell_00332961
- Gilead_Purcell_00332963
- Gilead_Purcell_00332968
- Gilead_Purcell_00332978
- Gilead_Purcell_00333008
- Gilead_Purcell_00333010
- Gilead_Purcell_00333071
- Gilead_Purcell_00333120
- Gilead_Purcell_00333123
- Gilead_Purcell_00333132
- Gilead_Purcell_00333136
- Gilead_Purcell_00333140
- Gilead_Purcell_00333142
- Gilead_Purcell_00333283
- Gilead_Purcell_00333324
- Gilead_Purcell_00333340
- Gilead_Purcell_00333352

- Gilead_Purcell_00333362
- Gilead_Purcell_00334335
- Gilead_Purcell_00006201
- Gilead_Purcell_00213107
- Gilead_Purcell_00201378
- Gilead_Purcell_00132422
- Gilead_Purcell_00132421
- Gilead_Purcell_00132499
- Gilead_Purcell_00132507
- Gilead_Purcell_00132508
- Gilead_Purcell_00336846
- Gilead_Purcell_00336848
- Gilead_Purcell_00336850
- Gilead_Purcell_00336849
- Gilead_Purcell_00281544
- Gilead_Purcell_00216678
- Gilead_Purcell_00216626
- Gilead_Purcell_00332123
- Gilead_Purcell_00132589
- Gilead_Purcell_00132635
- Gilead_Purcell_00132363
- Gilead_Purcell_00216564
- Gilead_Purcell_00276557
- Gilead_Purcell_00276515
- Gilead_Purcell_00276470
- Gilead_Purcell_00132692
- Gilead_Purcell_00324249
- Gilead_Purcell_00132287
- Gilead_Purcell_00324210
- Gilead_Purcell_00132564
- Gilead_Purcell_00132362
- Gilead_Purcell_00132590
- Gilead_Purcell_00308615
- Gilead_Purcell_00132509
- Gilead_Purcell_00332122
- Gilead_Purcell_00337167
- Gilead_Purcell_00337166
- Gilead_Purcell_00200291
- Gilead_Purcell_00154128
- Gilead_Purcell_00212683
- Gilead_Purcell_00212690
- Gilead_Purcell_00212685
- Gilead_Purcell_00200976
- Gilead_Purcell_00015140

- Gilead_Purcell_00192654
- Gilead_Purcell_00208886
- Gilead_Purcell_00210225
- Gilead_Purcell_00016290
- Gilead_Purcell_00268098
- Gilead_Purcell_00205973
- Gilead_Purcell_00205975
- Gilead_Purcell_00212691
- Gilead_Purcell_00212695
- Gilead_Purcell_00212694
- Gilead_Purcell_00197688
- Gilead_Purcell_00210712
- Gilead_Purcell_00013801
- Gilead_Purcell_00201336
- Gilead_Purcell_00032932
- Gilead_Purcell_00191515
- Gilead_Purcell_00191517
- Gilead_Purcell_00201340
- Gilead_Purcell_00201343
- Gilead_Purcell_00201350
- Gilead_Purcell_00013751
- Gilead_Purcell_00235173
- Gilead_Purcell_00247892
- Gilead_Purcell_00172581
- Gilead_Purcell_00247642
- Gilead_Purcell_00247645
- Gilead_Purcell_00247653
- Gilead_Purcell_00190426
- Gilead_Purcell_00240509
- Gilead_Purcell_00251733
- Gilead_Purcell_00314780
- Gilead_Purcell_00314782
- Gilead_Purcell_00314783
- Gilead_Purcell_00314943
- Gilead_Purcell_00314940
- Gilead_Purcell_00315193
- Gilead_Purcell_00317010
- Gilead_Purcell_00296607
- Gilead_Purcell_00317282
- Gilead_Purcell_00326133
- Gilead_Purcell_00132634
- Gilead_Purcell_00073651
- Gilead_Purcell_00281432
- Gilead_Purcell_00281433

- Gilead_Purcell_00012024
- Gilead_Purcell_00011965
- Gilead_Purcell_00206173
- Gilead_Purcell_00263618
- Gilead_Purcell_00180055
- Gilead_Purcell_00180058
- Gilead_Purcell_00017095
- Gilead_Purcell_00017103
- Gilead_Purcell_00206103
- Gilead_Purcell_00206104
- Gilead_Purcell_00206105
- Gilead_Purcell_00272273
- Gilead_Purcell_00254601
- Gilead_Purcell_00049444
- Gilead_Purcell_00025986
- Gilead_Purcell_00275523
- Gilead_Purcell_00275526
- Gilead_Purcell_00275528
- Gilead_Purcell_00275529
- Gilead_Purcell_00201604
- Gilead_Purcell_00337137
- Gilead_Purcell_00290431
- Gilead_Purcell_00177920
- Gilead_Purcell_00331207
- Gilead_Purcell_00331208
- Gilead_Purcell_00331210
- Gilead_Purcell_00331211
- Gilead_Purcell_00104748
- Gilead_Purcell_00104750
- Gilead_Purcell_00168522
- Gilead_Purcell_00320990
- Gilead_Purcell_00332071
- Gilead_Purcell_00332038
- Gilead_Purcell_00214391
- Gilead_Purcell_00332074
- Gilead_Purcell_00324621
- Gilead_Purcell_00270279
- Gilead_Purcell_00270282
- Gilead_Purcell_00213771
- Gilead_Purcell_00213774
- Gilead_Purcell_00333522
- Gilead_Purcell_00331049
- Gilead_Purcell_00191033
- Gilead_Purcell_00337006

- Gilead_Purcell_00191029
- Gilead_Purcell_00117960
- Gilead_Purcell_00253739
- Gilead_Purcell_00028915
- Gilead_Purcell_00028916
- Gilead_Purcell_00311270
- Gilead_Purcell_00132636
- Gilead_Purcell_00132638
- Gilead_Purcell_00202861
- Gilead_Purcell_00275597
- Gilead_Purcell_00275599
- Gilead_Purcell_00273985
- Gilead_Purcell_00274651
- Gilead_Purcell_00274653
- Gilead_Purcell_00202988
- Gilead_Purcell_00202989
- Gilead_Purcell_00203043
- Gilead_Purcell_00203055
- Gilead_Purcell_00203056
- Gilead_Purcell_00203062
- Gilead_Purcell_00203119
- Gilead_Purcell_00116845
- Gilead_Purcell_00116848
- Gilead_Purcell_00127845
- Gilead_Purcell_00129781
- Gilead_Purcell_00124193
- Gilead_Purcell_00124230
- Gilead_Purcell_00124240
- Gilead_Purcell_00124130
- Gilead_Purcell_00124156
- Gilead_Purcell_00124106
- Gilead_Purcell_00311209
- Gilead_Purcell_00003513
- Gilead_Purcell_00003517
- Gilead_Purcell_00003741
- Gilead_Purcell_00003745
- Gilead_Purcell_00003845
- Gilead_Purcell_00003849
- Gilead_Purcell_00003961
- Gilead_Purcell_00003981
- Gilead_Purcell_00004005
- Gilead_Purcell_00004021
- Gilead_Purcell_00122980
- Gilead_Purcell_00122972

- Gilead_Purcell_00123024
- Gilead_Purcell_00123029
- Gilead_Purcell_00003733
- Gilead_Purcell_00122976
- Gilead_Purcell_00007801
- Gilead_Purcell_00007840
- Gilead_Purcell_00007854
- Gilead_Purcell_00330984
- Gilead_Purcell_00330985
- Gilead_Purcell_00330993
- Gilead_Purcell_00330994
- Gilead_Purcell_00330998
- Gilead_Purcell_00007886
- Gilead_Purcell_00018798
- Gilead_Purcell_00007904
- Gilead_Purcell_00309140
- Gilead_Purcell_00309148
- Gilead_Purcell_00006709
- Gilead_Purcell_00006735
- Gilead_Purcell_00006730
- Gilead_Purcell_00006738
- Gilead_Purcell_00006739
- Gilead_Purcell_00006741
- Gilead_Purcell_00286876
- Gilead_Purcell_00308703
- Gilead_Purcell_00278115
- Gilead_Purcell_00277823
- Gilead_Purcell_00000802
- Gilead_Purcell_00006447
- Gilead_Purcell_00047283
- Gilead_Purcell_00103532
- Gilead_Purcell_00115659
- Gilead_Purcell_00116569
- Gilead_Purcell_00122920
- Gilead_Purcell_00134576
- Gilead_Purcell_00201020
- Gilead_Purcell_00216625
- Gilead_Purcell_00247920
- Gilead_Purcell_00252399
- Gilead_Purcell_00272572
- Gilead_Purcell_00278687
- Gilead_Purcell_00281003
- Gilead_Purcell_00284028
- Gilead_Purcell_00308613

- Gilead_Purcell_00319575
- Gilead_Purcell_00340625
- Gilead_Purcell_00253080
- Gilead_Purcell_00340638
- IQV-Gilead-000001
- IQV-Gilead-000036
- IQV-Gilead-000031
- IQV-Gilead-000032
- IQV-Gilead-000033
- IQV-Gilead-000034
- IQV-Gilead-000045
- IQV-Gilead-000051
- IQV-Gilead-000060
- IQV-Gilead-000061
- IQV-Gilead-000062
- IQV-Gilead-000064
- IQV-Gilead-000063
- IQV-Gilead-000077
- IQV-Gilead-000088
- IQV-Gilead-000259
- IQV-Gilead-000312
- REL_000389
- REL_000393
- REL_000449-61
- REL_000845
- REL_008536
- REL_005731
- REL_005733
- Gilead_Purcell_00135623
- Gilead_Purcell_00279861
- Gilead_Purcell_00279641
- Gilead_Purcell_00326972
- Gilead_Purcell_00247143
- Gilead_Purcell_00166517
- Gilead_Purcell_00279647
- Gilead_Purcell_00058341
- Gilead_Purcell_00058342
- Gilead_Purcell_00058343
- Gilead_Purcell_00249593
- Gilead_Purcell_00336057
- Gilead_Purcell_00335636
- Gilead_Purcell_00335779
- Gilead_Purcell_00336091
- Gilead_Purcell_00335625

- Gilead_Purcell_00336098
- Gilead_Purcell_00336093
- Gilead_Purcell_00334596
- Gilead_Purcell_00334598
- Gilead_Purcell_00334623
- Gilead_Purcell_00334605
- Gilead_Purcell_00336095